

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION |)))) <hr/>)) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: |)) | |
| SHEILA BROWN, et al. |)) | |
| v. |) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION |)) | 2:16 MD 1203 |

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 30, 2007

Alma J. Hickman ("Ms. Hickman" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In August 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Sheldon Litwin, M.D., F.A.C.C. Based on an echocardiogram dated August 17, 2002, Dr. Litwin attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension.³ Based on

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serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Litwin also attested that Ms. Hickman had mild aortic regurgitation. As Ms. Hickman's claim does not present any of the conditions necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$444,159.⁴

In the report of claimant's echocardiogram, Dr. Litwin stated that claimant had moderate mitral regurgitation, but did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Litwin also measured claimant's left atrial dimension as 5.4 cm in the apical four chamber view and 4.6 cm in the parasternal long axis view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Litwin found that claimant had a peak tricuspid regurgitation of 3.0 m/sec. Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral

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§ IV.B.2.c.(2)(a).

4. Initially, the Trust argued that claimant ingested diet drugs for less than sixty-one days and that, if eligible for benefits, claimant only would be entitled to payment based on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(b). In its Statement of the Case, however, the Trust appears to have abandoned this argument.

regurgitation is defined as peak systolic pulmonary artery pressure >40 mm Hg measured by cardiac catheterization or >45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.c.(2)(b)i).

In October 2003, the Trust forwarded the claim for review by George A. Davis, M.D., one of its auditing cardiologists. In audit, Dr. Davis concluded that there was no reasonable medical basis for Dr. Litwin's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In particular, Dr. Davis observed that:

The color gains were set high, and the low velocity frequency was set low, causing more color flow to be detected than normal, overestimating the amount of [mitral regurgitation]. Also, some low velocity nonaliasing signal was located within the tracing of the mitral regurgitant jet area, also causing an erroneously high RJA/LAA.

Dr. Davis, however, found that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension, which he measured as 5.3 cm in the apical four chamber view and 4.5 cm in the parasternal long axis view. Finally, Dr. Davis found that claimant had pulmonary hypertension, which he measured as 46.5 mm Hg.⁵

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. (continued...)

Based on Dr. Davis' diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Hickman's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that the auditing cardiologist inaccurately interpreted her August 17, 2002 echocardiogram tape. Claimant also submitted a supplemental opinion by Dr. Litwin, dated January 26, 2004, and an expert opinion by Brent McLaurin, M.D., F.A.C.C. In the supplemental opinion, Dr. Litwin stated that "[m]y interpretation of Alma Hickman's 8/17/2002 echocardiogram is true and correct." In the expert opinion, Dr. McLaurin stated that claimant "has severe mitral insufficiency that is directed posteriorly into the left atrium." Dr. McLaurin further stated that claimant "also has incidentally noted mitral annular calcification as well as aortic

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See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust concedes that there is a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension and pulmonary hypertension, each of which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hickman's claim.

sclerosis."⁷ Under the Settlement Agreement, the presence of mitral annular calcification ("MAC") requires the payment of reduced Matrix Benefits for a mitral valve claim. See Settlement Agreement § IV.B.2.d.(2)(c)ii)(d).

The Trust then issued a final post-audit determination, again denying Ms. Hickman's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hickman's claim should be paid. On December 6, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4197 (Dec. 6, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and

7. As the present claim is not based on damage to claimant's aortic valve, the presence of aortic sclerosis is not relevant to the disposition of this claim.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are
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claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35._____

_____The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).__

_____ In support of her claim, Ms. Hickman argues that the findings of Drs. Litwin and McLaurin establish a reasonable medical basis for her claim. Claimant also submitted several

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conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

still frames, which purportedly demonstrated moderate mitral regurgitation.

In response, the Trust argues that there is no reasonable medical basis for Dr. Litwin's finding of moderate mitral regurgitation because Dr. Davis found that Dr. Litwin relied on inaccurate settings and included low velocity flow in his measurements, both of which overestimated claimant's level of mitral regurgitation. The Trust also asserts that, if it is determined that Ms. Hickman has a compensable claim, Dr. McLaurin's finding of MAC reduces Ms. Hickman's Level II claim to Matrix B-1.⁹

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

Although there was excessive color flow gain, the severity of mitral regurgitation could be accurately determined. The MR jet was a central to laterally directed jet that intermittently traveled towards the back of the left atrium. I was able to accurately measure several representative frames of the mitral regurgitation in both the apical four chamber and apical two chamber views. The RJA/LAA was found to be between 22% and 28% in several cardiac cycles. Low velocity non-

9. The Trust also contends that the opinions of Drs. Litwin and McLaurin should be excluded because they are not verified. We disagree. While the Audit Rules allow for the submission of verified expert opinions, it does not preclude the submission of expert opinions that are not verified. See Audit Rule 18(b).

mitral regurgitant flow was not included in these measurements.

Dr. Vigilante also concluded that claimant's echocardiogram demonstrated the presence of MAC. In particular, he determined that:

There was definite evidence of mitral annular calcification noted in the posterolateral annulus in both the apical four chamber and apical two chamber views. This was manifested by increased reflectance and thickness of the posterolateral annulus classically seen with mitral annular calcification.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation. Claimant's attesting physician reviewed her echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust contested the attesting physician's finding of moderate mitral regurgitation, Dr. Vigilante confirmed the attesting physician's finding of moderate mitral regurgitation.¹⁰ Specifically, Dr. Vigilante concluded that "moderate mitral regurgitation was noted on the echocardiogram of August 17, 2002 even taking into account the issue of excessive color gain found on the study."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement

10. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Agreement § I.22. Here, Dr. Vigilante determined that claimant's RJA/LAA ratio was between 22% and 28% in both the apical four chamber and apical two chamber views. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's finding that she had moderate mitral regurgitation.

We, however, find that there is no reasonable medical basis for the attesting physician's finding that claimant does not have MAC. Under the Settlement Agreement, the presence of MAC requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Although Dr. Litwin did not attest to the presence of MAC on claimant's Green Form, claimant's own supplemental expert, Dr. McLaurin, asserted that claimant's echocardiogram demonstrated MAC. Dr. Vigilante concurred with Dr. McLaurin's finding of MAC by stating that "[t]here was definite evidence of mitral annular calcification noted in the posterolateral annulus in both the apical four chamber and apical two chamber views." Accordingly, the presence of MAC on claimant's August 17, 2002 echocardiogram reduces Ms. Hickman's Level II claim to payment on Matrix B-1.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. We, however, conclude that claimant has not met her burden in proving that there is a reasonable medical for finding that she does not have MAC. Therefore, we will reverse the Trust's denial

of the claim submitted by Ms. Hickman for Matrix Benefits, and find that Ms. Hickman consequently is entitled to Matrix B-1, Level II benefits.

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PRETRIAL ORDER NO.

AND NOW, on this 30th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Alma Hickman is entitled to Matrix B-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.